4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1694]

Determination That AVC (Sulfanilamide) Vaginal Cream, 15%, and Other Drug Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 006530	AVC	Sulfanilamide	15%	Cream; Vaginal	Mylan Specialty LP
NDA 007936	SELSUN	Selenium Sulfide	2.5%	Lotion/Shampoo; Topical	Chattem, Inc.
NDA 008816	XYLOCAINE	Lidocaine Hydrochloride	2%	Jelly; Topical	Akorn
NDA 009218	COUMADIN	Warfarin Sodium	1 Milligram (mg)	Tablet; Oral	Bristol Myers Squibb
NDA 012806	CORDRAN SP	Flurandrenolide	0.025%	Cream; Topical	Almirall
NDA 016647	QUINAGLUTE	Quinidine Gluconate	324 mg	Tablet, Extended Release; Oral	Bayer Healthcare
NDA 017386	ZAROXOLYN	Metolazone	2.5 mg; 5 mg; 10 mg	Tablet; Oral	Lannett Co., Inc.
NDA 017531	TIGAN	Trimethobenzamide Hydrochloride	300 mg	Capsule; Oral	King Pharms LLC
NDA 018081	DEPAKENE	Valproic Acid	250 mg	Capsule; Oral	AbbVie Inc.
NDA 018281	TEGRETOL	Carbamazepine	100 mg	Tablet, Chewable; Oral	Novartis
NDA 018303	LOPRESSOR HCT	Hydrochlorothiazide; Metoprolol Tartrate	25mg; 100mg	Tablet; Oral	Validus Pharms
NDA 018878	INDOCIN	Indomethacin Sodium	EQ 1 mg Base/Vial	Injectable; Injection	Recordati Rare Diseases
NDA 019404	OCUFEN	Flurbiprofen Sodium	0.03%	Solution/Drops; Ophthalmic	Allergan
NDA 019661	CYTOVENE	Ganciclovir Sodium	EQ 500 mg Base/Vial	Injectable; Injection	Cheplapharm
NDA 019697	ORTHO TRI-CYCLEN	Ethinyl Estradiol; Norgestimate	0.035 mg, 0.035 mg, 0.035 mg; 0.18 mg, 0.215 mg, 0.25 mg	Tablet; Oral	Janssen Pharms.
NDA 019766	ZOCOR	Simvastatin	80 mg	Tablet; Oral	Organon
NDA 019814	BETAGAN	Levobunolol Hydrochloride	0.25%	Solution/Drops; Ophthalmic	Allergan
NDA 019856	SINEMET CR	Carbidopa; Levodopa	25 mg, 100 mg; 50 mg, 200 mg	Tablet, Extended Release; Oral	Organon
NDA 019907	OPTIPRANOLOL	Metipranolol Hydrochloride	0.3%	Solution/Drops; Ophthalmic	Bausch and Lomb
NDA 019968	ULTRAVATE	Halobetasol Propionate	0.05%	Ointment; Topical	Sun Pharm Inds. Inc.
NDA 020010	LOTRISONE	Betamethasone Dipropionate; Clotrimazole	EQ 0.05% Base; 1%	Lotion; Topical	Merck Sharp Dohme
NDA 020381	NIASPAN	Niacin	500 mg; 750 mg; 1g	Tablet, Extended Release; Oral	AbbVie Inc.

NDA 020412	ZERIT	Stavudine	15 mg; 20 mg; 30 mg; 40 mg	Capsule; Oral	Bristol Myers Squibb
NDA 020509	GEMZAR	Gemcitabine Hydrochloride	EQ 200 mg Base/Vial; 1 Gram (g) Base/Vial	Injectable; Injection	Lilly
NDA 020593	DEPACON	Valproate Sodium	100 mg Base/Milliliter (mL)	Injectable; Injection	AbbVie Inc.
NDA 020615	DURACLON	Clonidine Hydrochloride	5 mg/10 mL (0.5 mg/mL)	Injectable; Injection	Mylan Institutional
NDA 020718	INTEGRILIN	Eptifibatide	2 mg/mL; 75 mg/ 100 mL	Injectable; Injection	Merck Sharp Dohme
NDA 021005	SOLARAZE	Diclofenac Sodium	3%	Gel; Topical	Fougera Pharms.
NDA 021085	AVELOX	Moxifloxacin Hydrochloride	EQ 400 mg Base	Tablet; Oral	Bayer Healthcare
NDA 021183	VIDEX EC	Didanosine	125 mg; 200 mg; 250 mg; 400 mg	Capsule, Delayed Release Pellets; Oral	Bristol Myers Squibb
NDA 021241	ORTHO TRI-CYCLEN LO	Ethinyl Estradiol; Norgestimate	0.025 mg, 0.025 mg, 0.025 mg; 0.18 mg, 0.215 mg, 0.25 mg	Tablet; Oral-28	Janssen Pharms.
NDA 021300	CLARINEX	Desloratadine	0.5 mg/mL	Solution; Oral	Merck Sharp Dohme
NDA 021312	CLARINEX	Desloratadine	2.5 mg; 5 mg	Tablet, Orally Disintegrating; Oral	Organon
NDA 021372	ALOXI	Palonosetron Hydrochloride	EQ 0.25 mg Base/5 mL (EQ 0.05 mg Base/mL); EQ 0.075 mg Base/1.5 mL (EQ 0.05 mg Base/mL)	Injectable; Intravenous	Helsinn Healthcare
NDA 021444	RISPERDAL	Risperidone	0.5 mg; 1 mg; 2 mg; 3 mg; 4 mg	Tablet, Orally Disintegrating; Oral	Janssen Pharms.
NDA 021455	BONIVA	Ibandronate Sodium	EQ 150 mg Base	Tablet; Oral	Hoffmann La Roche
NDA 021605	CLARINEX D 24 HOUR	Desloratadine; Pseudoephedrine Sulfate	5 mg; 240 mg	Tablet, Extended Release; Oral	Organon
NDA 021858	BONIVA	Ibandronate Sodium	EQ 3 mg Base/3 mL	Injectable; Intravenous	Hoffmann La Roche
NDA 021860	SARAFEM	Fluoxetine Hydrochloride	EQ 10 mg Base; EQ 20 mg Base	Tablet; Oral	Allergan
NDA 021956	DUTOPROL	Hydrochlorothiazide; Metoprolol Succinate	12.5 mg; EQ 25 mg Tartrate; 12.5 mg: EQ 50 mg Tartrate; 12.5 mg; EQ 100 mg Tartrate	Tablet, Extended Release; Oral	Concordia
NDA 022064	XYZAL	Levocetirizine Dihydrochloride	5 mg	Tablet; Oral	Chattem Sanofi

NDA 022106	DORIBAX	Doripenem	250 mg/Vial; 500 mg/Vial	Injectable; Intravenous Infusion	Shionogi, Inc.
NDA 022129	ULESFIA	Benzyl Alcohol	5%	Lotion; Topical	Shionogi, Inc.
NDA 022157	XYZAL	Levocetirizine Dihydrochloride	2.5 mg/5 mL	Solution; Oral	Chattem Sanofi
NDA 022321	EMBEDA	Morphine Sulfate; Naltrexone Hydrochloride	20 mg, 0.8 mg; 30 mg, 1.2 mg; 50 mg, 2 mg; 60 mg, 2.4 mg; 80 mg, 3.2 mg; 100 mg, 4 mg	Capsule, Extended Release; Oral	Alpharma Pharms.
NDA 050261	DECLOMYCIN	Demeclocycline Hydrochloride	75 mg; 150 mg; 300 mg	Tablet; Oral	Corepharma
NDA 050405	KEFLEX	Cephalexin	EQ 250 mg Base; EQ 500 mg Base; EQ 750 mg Base	Capsule; Oral	Pragma
NDA 050529	PEDIAZOLE	Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl	EQ 200 mg Base/5 mL; EQ 600 mg Base/5 mL	Granule; Oral	Ross Labs
ANDA 083082	CHLOROQUINE PHOSPHATE	Chloroquine Phosphate	250 mg; 500 mg	Tablet; Oral	Hikma Pharms.
NDA 204592	ZORVOLEX	Diclofenac	18 mg	Capsule; Oral	Zyla

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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